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**13. ABSTRACT (Maximum 200 Words)**

The objective of this pilot study is to develop informational messages about managing 6 common symptoms (nausea/vomiting, trouble sleeping, fatigue, trouble thinking, fever/chills, and pain), integrating them with a computer-based telephone symptom monitoring system, Telephone Linked Care (TLC) and then evaluating the usefulness of the TLC system and the informational messages during a cycle of chemotherapy for breast cancer. Using an experimental design with random assignment to the TLC program or standard care, participants in the experimental group will call the TLC system daily. Descriptive statistics and t-test will be used for analysis. The specific aims of the study are:

1. To test the feasibility of a computer-based telephone communication system (TLC) to provide informational messages about symptom management self care strategies for breast cancer patients during a cycle of chemotherapy.
2. To assess participant satisfaction, level of acceptability and the degree of difficulty in using the informational messages from the patient's perspective.
3. To compare the use of self care strategies, their perceived effectiveness and the source of information about the self care strategy between patients utilizing the TLC system and a control group receiving standard care.

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## INTRODUCTION

Today, most breast cancer treatment is provided on an outpatient basis. While this is both economical and preferable for most breast cancer patients, it presents logistical difficulties for providing adequate management of the side effects that result from these treatments. Cancer chemotherapy causes a variety of side effects that occur within hours to two or three weeks after treatment. Since patients are at home during this time, they must identify and manage their symptoms alone. This involves recognizing the symptoms, determining self-care activities to manage the symptoms and deciding when they need to contact the clinic for further assistance. Employing emerging telecommunication technology may help monitor symptom patterns and provide a method to coach cancer patients about self care strategies at the time they are experiencing specific symptoms (Greist, 1997; Friedman, Stollerman, Mahoney, Rozenblyum 1997). The objective of this pilot study was to develop informational messages about managing six common symptoms (nausea/vomiting, trouble sleeping, fatigue, trouble thinking, fever/chills, and pain) and then integrate them with a computer-based telecommunication system, Telephone Linked Care (TLC). We subsequently evaluated the usefulness of informational messages for patients receiving a cycle of chemotherapy for breast cancer. The specific aims of the study were:

1. To test the feasibility of a computer-based telephone communication system (TLC) to provide informational messages about symptom management self care strategies for breast cancer patients during a cycle of chemotherapy.
2. To assess participant satisfaction, level of acceptability and the degree of difficulty in using the informational messages from the patient's perspective.
3. To compare the use of self care strategies, their perceived effectiveness and the source of information about the self care strategies between patients utilizing the TLC system and a control group receiving standard care.

## BODY

Study Implementation and Procedure

The study has been conducted in three phases over the past three years. The first year was devoted to developing informational messages for the telephone script, and obtaining approval from the University of Utah Institutional Review Board and Department of Defense for enrollment of human participants. Delays in regulatory approval of the project lead to a no-cost one year extension to continue the study.

The second phase was completed in the second year. During the second phase, the telephone script was finalized, and incorporated into the TLC system. The Utah investigative team and the Boston informatics team, led by Robert Friedman M.D., collaborated on this carefully planned process. Once the system was in place, extensive testing was performed and modifications were made. The final version was submitted to the Department of Defense's Human Participants Research Review Board, who reviewed the study in July, 2002. Another no-cost extension was requested and granted to complete the final phase of the study.

The third and final phase of the study was completed in the last year. The Human Participants Research Review Board approved the study in September 2002, the first participant was enrolled in October 2002, and the final participant was enrolled in June 2003. All participants were patients with breast cancer receiving chemotherapy at the Huntsman Cancer Institute at the University of Utah on an outpatient basis. There were 40 participants who entered the study, 26 were on the experimental arm and 14 on the control arm.

For both arms of the study, the participants had to have completed at least one cycle of chemotherapy. Patients were screened either in the clinic or on the telephone by a research assistant. Eligible participants reported a mid-level of severity of at least one of the six symptoms outlined in this study. Once consent was obtained, the patients were randomized to the experimental or control arm. Those on the experimental arm were instructed to call the TLC system once daily for the length of one cycle of chemotherapy. Those on the control arm reported their symptoms as instructed by their physician and did not utilize the TLC system. End of study interviews were completed with both experimental and control groups.

## Results

The majority of the participants were Caucasian, married women with a mean age of 53. There was one male with breast cancer who participated in the study. See demographic details in the following Table 1:

Table 1 Demographics

| Demographics | Experimental (N=26) | | Control (N=14) | | Total (N=40) | |
|---|---|---|---|---|---|---|
| | Frequency | Valid Percent | Frequency | Valid Percent | Frequency | Valid Percent |
| ***Race*** | | | | | | |
| Asian/Pacific Islander | 1 | 3.8% | 0 | 0.0% | 1 | 2.6% |
| Black or African American | 1 | 3.8% | 0 | 0.0% | 1 | 2.6% |
| Caucasian | 24 | 92.3% | 12 | 100.0% | 36 | 94.7% |
| Missing | 0 | | 2 | | 2 | |
| ***Marital Status*** | | | | | | |
| Single (never married) | 2 | 7.7% | 1 | 8.3% | 3 | 7.9% |
| Separated or divorced | 2 | 7.7% | 0 | 0.0% | 2 | 5.3% |
| Married | 22 | 84.6% | 11 | 91.7% | 33 | 86.8% |
| Missing | 0 | | 2 | | 2 | |
| ***Cancer stage at diagnosis*** | | | | | | |
| Local | 7 | 31.8% | 6 | 50.0% | 13 | 38.2% |
| Regional | 13 | 59.1% | 3 | 25.0% | 16 | 47.1% |
| Advanced/Metastatic | 2 | 9.1% | 3 | 25.0% | 5 | 14.7% |
| Missing | 4 | | 2 | | 6 | |
| ***Extent of disease at present*** | | | | | | |
| Local | 3 | 13.0% | 5 | 35.7% | 8 | 21.6% |
| Regional | 12 | 52.2% | 2 | 14.3% | 14 | 37.8% |
| Advanced/Metastatic | 8 | 34.8% | 7 | 50.0% | 15 | 40.5% |
| Missing | 3 | | 0 | | 3 | |
| ***Present performance status*** | | | | | | |
| Asymptomatic | 14 | 58.3% | 5 | 55.6% | 19 | 57.6% |
| Symptomatic-fully ambulatory | 7 | 29.2% | 2 | 22.2% | 9 | 27.3% |
| Symptomatic in bed less that 50% of the day | 3 | 12.5% | 2 | 22.2% | 5 | 15.2% |
| Missing | 2 | | 5 | | 7 | |
| ***Age*** | Mean 51.58 | Std Deviation 9.95 | Mean 54.85 | Std Deviation 10.99 | Mean 52.67 | Std Deviation 10.28 |

Note: There were no significant differences in any of the variables between the experimental and the control group

Specific Aim 1:

To test the feasibility of a computer-based telephone communication system (TLC) to provide informational messages about symptom management self care strategies for breast cancer patients during a cycle of chemotherapy.

We were effective in developing self care strategies that were then successfully integrated into the TLC symptom monitoring system. Self care strategies were designed in several different ways. Some messages were programmed to be automatically given when a specific symptom threshold was reached. For example, if a patient reported a fever of 100.5 Fahrenheit or greater, TLC tells the person to call their doctor and report the fever. Other messages were offered the patient when a certain symptom pattern was present but the patient could choose to listen to the message or to skip it. For example, if a patient reported moderate levels of fatigue at least several days over the course of a week, she/he was told that research had shown that exercise, such as a walking program, can decrease fatigue in individuals receiving chemotherapy for breast cancer. Then the patient was asked if she/he would like to hear about starting an exercise program. If the patient said yes the message was played but if it was declined, the script continued to the next area. Some self care strategies were broken into small listening sessions that, once elected by a patient, would automatically offer the next session during each successive phone call. For example there were a series of suggestions regarding energy conservation which once elected by a patient were made available over a series of 6 days. For some symptoms, patients were told of several strategies they could try and then were asked to pick one they wanted more detail on. For example, if they reported trouble sleeping they could elect from 5 different strategies to improve their sleeping. Finally all self care strategies were available in a "library" menu that patients could elect to listen to at the end of any telephone session. We found it feasible to take standard self care strategies for chemotherapy related symptoms and integrate them in a variety of formats into the TLC system. Self care strategies that were triggered by complex symptom patterns or were presented in multiple components required longer programming time but were still able to be integrated into TLC.

Specific Aim 2:

To assess participant satisfaction, level of acceptability and the degree of difficulty in using the informational messages from the patient's perspective.

All but three participants in the experimental group had 19-day chemotherapy cycles. The range was between 18 and 27 days per cycle. The mean phone compliance was 65%, meaning the participants called on average 12 or 13 days out of the 19 day cycle. The range was a low of 21% completed calls and a high of 100% completed calls.

Participants in the experimental group reported a variety of symptoms. The most commonly reported symptoms were sleep disturbance (93%) and fatigue (89%). Next most common were feeling blue (74%), distress over appearance (70%), and nausea and

vomiting (70%). Table 2 provides a summary of symptom frequency, severity, distress, and range of days that participants in the experimental group reported symptoms.

Table 2: Experimental Group Symptom Experience as Reported to TLC

| Symptom | Prevalence | Mean Severity (1-10) | Severity Range (1-10) | Mean Distress Over Symptom (0-10) | Mean # of Days Reported | Range of Days Reported |
|---|---|---|---|---|---|---|
| Trouble Sleeping | 93% | 4.49 | 1 - 10 | 4.27 | 5 | 1 - 8 |
| Fatigue | 89% | 4.28 | 1 - 10 | 3.92 | 7 | 1 - 20 |
| Feeling Blue | 74% | 4.18 | 1 - 9 | 4.0 | 2 | 1 - 11 |
| Distress Over Appearance | 70% | 1.21 | 1 - 2 | 6.25 | 3 | 1 - 18 |
| Nausea/Vomiting | 70% | 2.87 | 1 - 10 | 2.77 | 5 | 1 - 16 |
| Feeling Anxious | 65.5% | 3.45 | 1 - 5 | 3.42 | 2 | 1 - 3 |
| Trouble Thinking or Concentrating | 52% | 3.53 | 1 - 7 | 3.6 | 3 | 1 - 11 |
| Pain | 46% | n/a | n/a | n/a | n/a | n/a |
| Diarrhea | 41% | 3.67 | 1 - 9 | 3.92 | 3 | 1 - 12 |
| Sore Mouth | 36% | 2.97 | 1 - 8 | 3.17 | 4 | 1 - 10 |
| Fever | 30% | n/a | n/a | n/a | n/a | n/a |
| Extremity Numbness/Tingling | 25% | n/a | n/a | n/a | n/a | n/a |
| Aches | 24% | n/a | n/a | n/a | n/a | n/a |

Note: pain, numbness/tingling and aches were asked as a combined question about discomfort. Prevalence data are available but not severity or distress data

Participants in the experimental group reported multiple symptoms that were mild to moderate in severity, were present approximately 15% – 38% of their treatment cycle and caused moderate levels of distress.

The majority of experimental participants indicated that TLC's advice about symptom management was helpful- 74% said it was somewhat to totally helpful and 58% said it helped a great deal to totally. When asked what was most helpful, 60 % of participants said the suggestions related to fatigue, another 15% identified the suggestions to improve sleep and another 15% said all of the suggestions were helpful because they helped to normalize the experience and prioritize how to adapt their life to cope with the treatment side effects. All but three participants said that they tried the advice given to them by TLC. The suggestions tried included exercise, energy conservation, dietary changes, environmental changes to improve sleep, taking sleeping medication and contacting their doctor with questions. Fifty percent of the experimental participants said they elected to listen to self care suggestions out of the end-of-call library menu one or two times during the course of their treatment cycle.

Almost all participants indicated that TLC was easy to learn. About one-third of the participants indicated that on one or more calls they had difficulty connecting with TLC or were disconnected during the call. One participant indicated she felt too sick to make calls. Several participants suggested that TLC be streamlined and have an option to quickly report that nothing had changed in their symptom profile rather than systematically going through the drill down. Several participants suggested other symptoms that could be added to TLC. Two participants suggested that TLC be adapted so that a participant could request supplemental written materials be sent to them.

Specific Aim 3:

To compare the use of self care strategies, their perceived effectiveness and the source of information about the self care strategies between patients utilizing the TLC system and a control group receiving standard care.

The control group (N = 14) reported considerably fewer symptoms on interview after completing their cycle of chemotherapy. Control group participants only reported prevalence on five of the fourteen symptoms with fatigue reported with a mean severity of 6.8 (1-10 rating) by 71% of participants and nausea with a mean severity of 7 reported by 50% of participants. This may occur because the control group had to recall symptoms that had occurred days earlier and the interview was conducted before they had additional chemotherapy and were feeling well. In addition participants calling TLC reported that it helped them think about their symptom experience whereas the control group had nothing to help them follow their symptom experience. There were too few symptoms or severity ratings to perform statistical comparisons however it does appear that the recollection of control group participants may be quite different from those utilizing TLC.

Both groups consulted a variety of resources to learn about symptom care strategies. Physicians and nurses were the most common resource cited by both groups (other than TLC for experimental participants). The experimental group of participants consulted as many sources as did the control group with an average rating of helpfulness of the advice between 3 and 4 on a 5 point rating scale for both groups.

## Key Research Accomplishments

- Developed self-care strategies for six common symptoms resulting from chemotherapy for breast cancer.
- Developed an operational computer-based telephone system, TLC, which monitors and provides feedback on self-care strategies for chemotherapy related symptoms during breast cancer treatment.
- Validated the feasibility of the TLC system, along with patient satisfaction and ease of use.

## REPORTABLE OUTCOMES

Two abstracts have been submitted to national/international conferences and are currently under review:

1. Mooney, K., Beck, S., Dudley, W., Farzanfar, R., Friedman, R. A Computer-Based Telecommunication System to Improve Symptom Care for Women with Breast Cancer
   Submitted to the Society of Behavioral Medicine Annual Meeting and Scientific Sessions, Baltimore Maryland, March 24-27, 2004

2. Mooney, K., Beck, S., Farzanfar, R., Friedman, R., Dudley, W. Improving Symptom Care Through Home Linked Technology
   Submitted to the 13th International Conference on Cancer Nursing, The International Society of Nurses in Cancer Care, Sydney, Australia, August 8-12, 2004

## CONCLUSIONS

Initial feasibility and applicability was demonstrated for the TLC system as a means to provide self care strategies for individuals at home who are experiencing symptoms related to breast cancer treatment. Based on participant feedback, modifications will be made in the TLC script to allow streamlined responses. In addition, further refinements will be made so that the TLC system can track the effectiveness of the interventions adopted by the user. Further testing is now indicated with a sample size that provides adequate power to determine if the TLC system improves symptom relief over conventional approaches to symptom management for individuals receiving treatment for breast cancer.

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# APPENDICES

None.